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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,483	07/09/2003	Valentino Montegrando	0424-02	9699

21704 7590 06/15/2004
LAW OFFICES OF ERIC KARICH
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EXAMINER

YANG, NELSON C

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,483

Applicant(s)

MONTEGRANDE ET AL.

Examiner

Nelson Yang

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/8/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 1 objected to because of the following informalities: the word “an” in line 1 is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 5, 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 10 recite the limitation of an electronic reader apparatus adapted for making an electronic connection with an electrode. It is unclear what structural or physical characteristics would be encompassed by the term “adapted” to render the electronic reader apparatus capable of making an electronic connection with the electrode.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1641

5. Claims 1-5, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Madou et al [US 4,874,500].

With respect to claims 1-4, 11, Madou et al teach a microelectrochemical sensor array comprising wells with electrodes located within the wells (column 2, lines 45-60), made using microfabrication techniques (column 3, lines 10-15). Madou et al further teach that composite membranes containing antigen-antibody materials can be placed within the wells (column 7, lines 30-35).

6. With respect to claim 5, Madou et al teach electronic circuitry adapted for processing signals from the sensing electrodes for detecting concentrations of species being detected (column 12, lines 20-41).

7. Claims 1, 3-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Chow [US 6,167,910].

With respect to claims 1, 3-11, Chow et al teach multi-layer microfluidic devices comprising channels and wells (column 3, lines 1-26), including a common sample port (inlet well) and waste reservoir (outlet well) (column 7, lines 50-67) using microfabrication techniques (column 6, lines 14-40). Chow et al further teach the use of detection systems such as electrochemical sensors (electrodes) in connection with a computer (column 12, lines 29-60). Chow et al also teach the use of antibodies in the microfluidic device (column 12, lines 60-65).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1641

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chow et al [US 6,149,787].

Chow et al teach the use of electrochemical sensors (electrode) as discussed above. Chow et al do not teach that the sensors are micro-fabricated as part of the substrate.

Madou et al, however, do teach the microfabrication of microelectrochemical sensors (column 1, lines 5-15). Madou et al, further teach that these electrode structures are characterized by extremely small size, low power utilization, fast response time, operable at room temperature, and readily mass produced (column 3, lines 5-15). Therefore it would have been obvious in the device of Chow et al for the electrochemical sensors to be microfabricated, as suggested by Madou et al, in order to obtain electrodes characterized by small size, low power utilization, fast response time, operable at room temperature, and readily mass produced.

Conclusion

10. No claims are allowed.

11. The following references are also cited as art of interest: Moles [US 5,932,799], Moles [US 6,073,482] teach microfluidic flow devices with sensing elements disposed within sensing channels, Chow [US 6,167,910] teaches a microfluidic device with electrochemical detectors, Spring et al [US 5,643,721] teach a immobilization medium involving specific binding members such as antibodies and antigens, Mian et al [U 6,319,469] teaches microfluidic devices for microanalytical and microsynthetic processes.

Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

06/14/04